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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,219	07/09/2001	Mark S. Schaberg	54670USA1A.002	6255

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/26/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/901,219	SCHABERG ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' request under 1.114 and amendment A, both filed 06/24/2003.

Claim 6 has been canceled.

Claims 1-5, 7-30 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/24/2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,966,902 ('902).

US '902 teaches a composition comprising a drug in a polymer carrier (abstract). The polymer comprising pyrrolidonoethyl methacrylate polymerized with alkyl acrylate monomer and monomer comprising carboxylic acid (col.2, lines 30-32, 57-58; col.3, lines 1-2, 20-22). The number of carbon atoms is inherent for the monomer.

The reference does not teach pyrrolidonoethyl acrylate, but the species pyrrolidonoethyl methacrylate.

It is within the skill in the art to replace one species by another if it known that that they perform the same function. No superior and unexpected results of record showing the criticality of using pyrrolidonoethyl acylate.

Thus, it would have been obvious to one having ordinary skill in the art at he time the invention was made to replace pyrrolidonoethyl methacrylate by pyrrolidonethyl acrylate since both are adhesives, with reasonable expectation of having a composition with improved adhesiveness.

5. Claims 1-5, 7-18, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '902 in view of any of US 6,193,996 ('996) or WO 96/08229 ('229).

US '902 teaches a composition comprising a drug in a polymer carrier (abstract). The polymer comprising pyrrolidonoethyl methacrylate polymerized with alkyl acrylate monomer and monomer comprising carboxylic acid (col.2, lines 30-32, 57-58; col.3, lines 1-2, 20-22). The number of carbon atoms is inherent for the monomer.

The reference does not teach the macromonomer, the backing for the transdermal delivery, or the species of the alkyl acrylate.

US '996 teaches a pressure sensitive comprising a copolymer of one or more alkyl acrylates or (meth)acrylates containing 4-12 carbon atoms and one or more hydrophilic monomers. Examples of the alkyl acrylates include butyl, isooctyl, cyclohexyl and 2-ethylhexyl acrylates (abstract; col.2, lines 53-66). Hydrophilic monomers include carboxylic acid containing monomers, vinyl acetate and amino containing monomer (col.3, lines 1-14). The copolymer further comprising macromer, such as polymethylmethacrylate and softener, such as ethylene glycol and propylene glycol (col.3, lines 30-67); col.4, line 61). The adhesive composition comprises pyrrolidone

derivatives (col.2, line 30). The above composition is applied into a backing (col.5, lines 21-24).

WO '229 discloses a transdermal drug delivery device comprising a pressure sensitive adhesive comprising copolymer of monomers selected from alkyl acrylate containing 4-12 carbon atoms; monomers comprising functional groups selected from carboxylic acid, sulfonamide, urea, carboxamide, amine, oxy oxo, and cyano; macromonomer; drug; and softener (page 79, lines 1-25). The copolymer further comprises vinyl acetate or pyrrolidones in an amount of 0-60% (page 80, lines 1-14, 27-30). The alkyl acrylate is selected from isooctyl acrylate, ethylhexyl acrylate, butyl acrylate and cyclohexyl acrylate (page 80, lines 23-25). The macromonomer is present in an amount not more than 15% and is selected from the group containing polymethylmethacrylate (page 81, lines 15-16; page 82, lines 15-18). The softener is present in an amount of 20-60% and selected from fatty acids and fatty alcohols (page 82, lines 20-30).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the adhesive composition disclosed by US '902 and add the additional monomers and the macromonomers disclosed by US '996 and WO '229 to the copolymer of US 902, motivated by the teaching of WO '229 that the copolymer of the invention comprising functional monomers and macromonomers provides an adhesive that maintains contact with the skin and can be removed cleanly from the skin (page 3, lines 11-15), or motivated by the teaching of US '996 that the adhesive of the copolymers allow to maintain the device in contact with the skin for a sufficient time

(col.2, lines 45-48), with reasonable expectation of having a transdermal drug delivery device with sufficient adhesiveness and drug flux through the skin.

6. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '902 in view of US '966 or WO '22 as applied to claims 1-5, 7-18 and 25-30 above, and further in view of US 2002/0110585 ('585).

The rejection over US'902 in view of US '966 or WO '229 is discussed above.

However, the references in combination do not teach the specific antimicrobial drugs as claimed in claims 19-24. .

US '585 teaches a transdermal drug delivery device comprising a reservoir comprising copolymer of alkyl methacrylate and monomer having functional group selected from carboxylic acid, sulfonamide, oxy oxo, amine, carbamate, carboxamide, or urea (abstract; page 4, 0039-0041). The drugs to be delivered in this reservoir include iodine compounds and chlorohexidine (page 8, 0101).

Thus, it would have been obvious to one having ordinary skill in the art at he time of the invention to deliver drug delivery device as disclosed by US '902 in view of US '966 or WO '229, and select chlorohexidine as the active agent to be delivered transdermally as taught by US '585, with reasonable expectation of having a drug delivery device to deliver chlorohexidine transdermally with success.

Response to Arguments

7. Applicant's arguments filed 06/24/2003 have been fully considered but they are not persuasive.

Applicant's main argument is that the references do not teach pyrrolidonoethyl acrylate.

In response to the above argument, the examiner position is that the reference teaches the generic concept of using alkyl acrylate and pyrrolidone monomer, and it is within the skill in the art to select species when the art discloses the genus and some species. No criticality has been shown in using PyEA over PyMEA. The alkyl group suggests any number of carbon atoms that encompass 4-12. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983). A reference may be relied upon for all that it would have reasonable suggested to one having ordinary skill in the art, including nonpreferred embodiments.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600